## Summary of the Joint Meeting of the Program Policy and Structure and the Accrediting Authority Committees February 4, 1997

The Program Policy and Structure Committee and Accrediting Authority Committees met in a joint session on February 4, 1997. The meeting was led by Dr. Kenneth Jackson of the New York State Department of Health and Mr. John Anderson of the Illinois EPA Division of Laboratories, chairs of the respective committees. The purpose of the meeting was to discuss issues related to unconditional reciprocity. Discussion concerned information contained in Section 1.6.2 (and pertinent subsections), Section 1.6.3, and Section 6.2 of the NELAC draft standards.

## **Unconditional Reciprocity**

The issue of unconditional reciprocity stems from a draft that included one line about reciprocity. Discussion began by noting the use of the terms "primary and secondary" accreditation. It was agreed that Chapter 6 will be revised to include this distinction consistent with Chapter 1.

Two questions were raised:

- 1. What stipulations can be imposed by a secondary accreditation authority on a laboratory accredited by a primary accrediting authority?
- 2. How does a secondary accrediting authority deal with stipulations on a laboratory by a primary authority?

The group was reminded that Section 1.6.2.3.1 states that a laboratory's home State has full responsibility for granting accreditation to that laboratory and may also serve as the primary accrediting authority for work that the lab conducts in other States that do not regulate that activity. It was noted that accreditation is a determination of competency and that legal recourse must be undertaken by regulators. An accreditation authority can suspend certification but cannot enforce other legal requirements of another State.

A question was raised about the recourse available to a secondary accrediting authority when a violation is discovered. Another person questioned whether a laboratory can be barred from accreditation in one State if it's accreditation has ben revoked by another State. Laws and regulations will be the purview of each State. The NELAP national database will provide information on laboratory accreditation status.

Must each State have mechanisms for addressing revocations for violations of State law? It was pointed out that Section 1.6.2.3 covers this issue.

Are violations of law covered under unconditional reciprocity? Does a suspension hold from one state to another? If a laboratory is suspended, it should be reported to all parties involved-this

allows individual States to decide how to respond. The State will have to decide how to address this problem when NELAC is implemented. However, it must take appropriate action when NELAC standards are not maintained.

Laboratories must be judged by NELAC standards by both primary and secondary accrediting authorities. For example, if a laboratory fails two out of three proficiency tests, the primary authority is obligated to suspend the labs and notify the secondary accrediting authority.

A participant commented that secondary accreditation is granted by fields of testing, which is addressed in Chapter 1. States can only grant secondary accreditation for fields in which they grant primary accreditation. If a State does not regulate labs in a specific field, then the lab does not need to be accredited in that State for that field.

Reciprocity can only be granted by NELAP-accredited States, but a State can enact regulations that require that only NELAP labs be used in that State. NELAP standards may become part of State law in some States.

The question was raised: If State law is violated but no NELAP standards are violated, what happens? NELAP does not address the violation. All NELAP violations should be reported from secondary authorities to primary authorities and vice versa.

It was commented that NELAP standards should include language that violations noted by a secondary authority must be reported to the primary authority. Comment was made that there needs to be assurances that a primary authority will deal with a reported problem within a specified time. What happens to a lab in the interim once a problem has been reported? Accrediting authorities should respond to complaints from all sources.

Section 1.6.1.2, page 10, states that unconditional reciprocity between States may need to add language to clarify State regulations versus NELAP standards.

How will the program deal with 50 States having 50 different requirements for a particular field? The U.S. Environmental Protection Agency (USEPA) must deal with this issue. A participant commented that reciprocity is the heart of NELAC and cooperation between all parties is essential.

It was noted that Section 6.2(J), page 4, needs clarification from USEPA. This issue was addressed in the Accrediting Authority Committee.

The role of Indian tribes is complicated. This was not solved and talks are ongoing.